PATENT
Attorney Docket No. 61169

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Mary R. Flack et al.

Serial No. 08/379,872

Filed: January 27, 1995

Group Art Unit: 1614

Examiner: J. Goldberg

For: Gossypol For The Treatment Of Cancer

DECLARATION UNDER 37 CFR § 1.132

Assistant Commissioner For Patents
Washington, D.C. 20231

Sir:

I, Marcus Reidenberg, declare as follows:

1. I am a co-inventor of the subject matter that is disclosed and claimed in the matter of the above-identified application, and I am an expert in the field of the present invention as evidenced by the attached copy of my *curriculum vitae.*

2. I am familiar with the application and the pending claims.

3. I am familiar with the Office Action of February 27, 1998, and have analyzed and am familiar with Kim et al., Contraception *312*: 5966-72 (1984), Qian et al., Ann. Rev. Pharmacol. Toxicol. *24*: 329-60 (1984), Rao et al., Cancer Chemother. Pharmacol. *15*: 20-25 (1985), Tso, Cancer Lett. *24*: 257-261 (1984), and Band et al., Gynecol. Oncol. *32*: 273-277

(1989) upon which claims 1, 3, 4, 13-16, and 20-23 stand rejected.

4. Qian et al. and Kim et al. do not relate to the treatment of cancer. Rather, they are directed to the spermicidal effects of gossypol.

5. Band et al. teaches that gossypol inhibits the proliferation of cancerous and non-cancerous cells *in vitro*, concluding that gossypol "acts as a general and nonselective antiproliferative agent" (Band et al., page 276, col. 2 through page 277, col. 1). Successful anticancer drugs selectively kill tumor cells; if anticancer drugs killed cells indiscriminately, the cure would be worse than the disease.

6. Given the general toxicity of gossypol to both normal and cancerous human cells *in vitro* as disclosed by Band et al., one of ordinary skill in the art, upon reading that reference, would reasonably conclude that gossypol would be toxic to cancerous and noncancerous human cells *in vivo*.

7. Rao et al. relates to the treatment of cancer in mice. Rao et al. reports that gossypol was completely ineffective against two of the three tumor models tested. In the other tumor line, gossypol could be safely and effectively administered within only a very narrow dosage range. Thus, although a dosage of 0.5 mg/mouse was reportedly effective, at

0.4 mg/mouse, the efficacy was reduced by more than half, and at 0.6 mg/mouse, nearly two-thirds of the mice died due to gossypol toxicity. In other words, at dosages 0.8 times optimal, gossypol was a relatively poor anticancer agent, and at dosages 1.2 times optimal, gossypol was lethal.

8. While Tso also relates to the treatment of cancer in mice, Tso teaches the use of gossypol to treat tumors that do not even occur in humans (Ehrlich ascites tumors). In analogy to Rao et al., however, Tso reports that gossypol could be safely and effectively administered within only a very narrow dosage range. Although a daily dosage of 25-100 μg of gossypol was found to be relatively safe and effective, with 100 μg being optimal, when the dosage was increased to 250 μg/day, all of the treated mice died due to gossypol toxicity. Thus, at a dosage only 2.5 times the reported optimal therapeutic dosage, gossypol was lethal.

9. In view of the *in vitro* toxicity of gossypol to both cancerous and noncancerous human cells as reported by Band et al., and given that gossypol was found by Rao et al. and Tso to be lethal in mice at doses only marginally higher than the reported optimal therapeutic doses, one of ordinary skill in the art, would not only reasonably conclude that gossypol would be toxic to cancerous and noncancerous human cells *in vivo* but would also not be motivated to try gossypol or any other compound encompassed by the claims in the treatment of

human cancer, let alone reasonably expect that such compounds would be safe and effective anti-cancer drugs. Therefore, it is my opinion that, considering the cited references at the time that the present invention was made, one of ordinary skill in the art would not have believed that it would be possible to determine successfully a safe and effective dosage range in genetically heterogeneous humans for a drug that displays such a general toxic effect *in vitro*, and such a narrow window of efficacy and safety in a genetically homogeneous population of in-bred rodents.

10. I hereby declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patents issued therefrom.

Date: 5/27/98 By: Marcus Reldenberg

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CURRICULUM VITA

Marcus Milton Reidenberg

Born: Philadelphia, Pennsylvania
January 3, 1934

Married: 1957

CURRENT POSITIONS

Cornell University Medical College New York, NY	Professor of Pharmacology Professor of Medicine and Head, Division of Clinical Pharmacology Assistant Dean, Departmental Associates Program
The New York Hospital New York, NY	Attending Physician
Rockefeller University New York, NY	Visiting Physician

PREVIOUS POSITIONS

Cornell University Medical College New York, New York	1981-1982, Acting Associate Dean 1976-1980, Professor of Pharmacology/Associate Professor of Medicine, and Head, Division of Clinical Pharmacology
The New York Hospital New York, New York	1975-1980, Associate Attending Physician
Rockefeller University New York, New York	1975-1977, Visiting Associate Physician
Cornell University Medical College New York, New York	1975-1976, Associate Professor of Pharmacology/Associate Professor of Medicine
Temple University Philadelphia, Pennsylvania	1972-1974, Associate Professor of Pharmacology/Associate Professor of Medicine and Head, Section of Clinical Pharmacology
Temple University Philadelphia, Pennsylvania	1971-1972, Associate Professor of Pharmacology/Assistant Professor of Medicine and Head, Section of Clinical Pharmacology

Department of Biochemistry St. Mary's Hospital Medical School London, England	1969-1970, Visiting Scientist with Professor R.T. Williams
Department of Clinical Pharmacology Karolinska Institutet Stockholm, Sweden	1970, Visiting Scientist with Professor Folke Sjoqvist
Temple University Philadelphia, Pennsylvania	1967-1971, Assistant Professor of of Pharmacology and Internal Medicine
	1965-1967, Assistant Professor of Pharmacology, Instructor of Internal Medicine
	1965, Instructor of Pharmacology, Instructor of Internal Medicine
	1962-1965, Instructor of Pharmacology, Resident in Internal Medicine
U.S. Navy	1960-1962, Senior Medical Officer U.S. Naval Station, Trinidad
Temple University Philadelphia, Pennsylvania	1959-1960, U.S.P.H.S. Postdoctoral Fellowship in Pharmacology with Dr. R. W. Sevy
Community General Hospital Reading Pennsylvania	1958-1959, Internship
Temple University Philadelphia, Pennsylvania	1955-1958, Summer Student Research Fellow in Physiology and Pharmacology with Drs. E. A. Ohler and R. W. Sevy
	1954-1958, Medical School (M.D., 1958)
Cornell University Ithaca, New York	1951-1954, Pre-medical (no degree)

SOCIETY MEMBERSHIP

Association of American Physicians

American Society for Clinical Investigation

American College of Physicians (Fellow)

Society for Experimental Biology and Medicine

American Society for Pharmacology and Experimental Therapeutics

American Society of Tropical Medicine and Hygiene

American Society for Clinical Pharmacology and Therapeutics

American Federation for Clinical Research

International Association for the Study of Pain

Sigma Xi

The Harvey Society

The New York Academy of Sciences

The American Society of Nephrology

American Association for the Advancement of Science

Council on Basic Science, American Heart Association

Royal Society of Tropical Medicine and Hygiene

Royal Society of Medicine (Fellow)

American Geriatrics Society

LICENSES AND CERTIFICATIONS AND AWARDS

License to Practice Medicine in Pennsylvania and New York.

Certified by American Board of Internal Medicine, December 7, 1967.

Fred Conrad Koch Travel Fellow of The Endocrine Society Award, 1968.

Research Career Development Award, National Institute of General Medical Sciences, National Institutes of Health, 1970-1974.

Temple University S.A.M.A. Teacher Recognition ("Golden Apple") Award, 1973.

Rawls-Palmer Award of the American Society for Clinical Pharmacology and Therapeutics, 1981.

Experimental Therapeutics Award of the American Society for Pharmacology and Experimental Therapeutics, 1983.

William Creasy Visiting Professor of Clinical Pharmacology at the University of Oregon Medical School, 1981; University of Cincinnati Medical School, 1984.

Julius W. Sturmer Memorial Lecture Award of the Philadelphia College of Pharmacy and Science, 1982.

Cornell University Medical College Second Year Teaching Award, 1986, 1992.

Temple University Medical School Alumni Achievement Award, 1988.

Cornell University Medical College Alumni Association Honorary Fellowship, 1993.

The Departmental Associates of The New York Hospital-Cornell Medical Center established a program to provide minority college students with summer research opportunities and named it the Marcus M. Reidenberg Gateways to Science Program, 1993.

Pfizer Visiting Professor of Clinical Pharmacology, Meharry Medical College, 1995.

EXTRACURRICULAR ACTIVITIES

World Health Organization
- Expert Advisory Panel on Drug Evaluation, Member 1989-1993, 1993-1997
- Expert Committee on the Use of Essential Drugs, Rapporteur, 1989
- Temporary Advisor, WHO International Drug Monitoring Program, 1990
- Expert Committee on the Use of Essential Drugs, Rapporteur, 1991
- Expert Committee on the Use of Essential Drugs, Rapporteur, 1993
- Temporary Advisor, Special Program of Research, Development, and Research Training in Human Reproduction, 1992
- Advisor about Essential Drugs Program, Ministry of Health, People's Republic of China, 1993

American College of Physicians
- Chairman, Ad Hoc Committee on Clinical Pharmacology, 1971
- Chairman, Committee on Clinical Pharmacology, 1972-1977
- Member, MKSAP VI Committee, 1980-1982
- Director, C.M.E. Course, Individualization of Drug Therapy, 1973
- Director, C.M.E. Course, The Clinical Pharmacology of Symptom Control, 1982

American Society for Pharmacology and Experimental Therapeutics
- Member of Executive Committee, Division of Clinical Pharmacology, 1971-1978, 1980-
- Acting Chairman, Executive Committee, Division of Clinical Pharmacology, 1972
- Membership Committee, 1979-1982; Chairman, 1981-1982
- Educational Affairs Committee, Chairman of Subcommittee on Continuing Medical Education, 1980-1981
- Program Chairman for Second World Congress on Clinical Pharmacology, Washington, D.C., July-August 1983
- Nominating Committee, 1984
- Member, Board of Publications Trustees, 1985-

International Union of Pharmacology
Member, Working Group on Drug Metabolism, 1982-1984
Vice Chairman, Section on Clinical Pharmacology, 1984-1987
Chairman, Section of Clinical Pharmacology, 1987-1989
Immediate Past Chairman, Section of Clinical Pharmacology, 1989-1992
Member, Working Group to Review IUPHAR Statutes, 1988
Auditor, 1990-1993
Member, International Advisory Committee, World Conference on Clinical Pharmacology of 1992
Member, International Advisory Committee, World Conference on Clinical Pharmacology of 1996
Member, Membership Committee, 1990-1993

American Society for Clinical Pharmacology and Therapeutics
Board of Directors, 1975-1977, 1979-1982, 1986-
Vice President, 1982-1983
President Elect, 1983-1984
President, 1984-1985
Multiple Committee Memberships, 1980-

Consultant, South-to-South Cooperation in Reproductive Health, 1991-

Chairman, Session on Clinical Pharmacokinetics, Gordon Research Conference on Drug Metabolism, 1971 and 1976

Consultant to Drug Research Board, National Academy of Sciences-National Research Council, 1968-1970

Food and Drug Administration
Consultant, 1971
Member, Project Advisory Group, Experiment in Early Postmarketing Surveillance of Drugs, 1977-1982
Invited Expert, Fertility and Maternal Health Drugs Advisory Committee, 1990
Member, Over-The-Counter (OTC) Drugs Advisory Committee, 1992-1995.

Consultant, Walter Reed Army Medical Center, 1974-1977

National Institutes of Health
Special Study Section, 1980 and 1986
Task Force on Geriatric Medicine, 1980
Pharmacological Sciences Review Committee (Study Section), 1980-1985
Workshop Chairman, Program Initiatives in Gerontological Pharmacology 1981
Consensus Conference on Pain Management Panel Member, 1986
Epidemiology and Disease Control Special Study Section, 1990
Data Safety Monitoring Review Committee for MIRA trial, 1991-1993

Joint Commission on Prescription Drug Use, Member, 1976; Vice Chairman, 1977-1980

Consultant, Hoffmann-La Roche, Inc., 1975-

Consultant, Genta, Inc. 1994-

Association of American Medical Colleges Ad Hoc Committee on AAMC/FDA Interactions, 1978-1982

Merck Company Foundation
International Clinical Pharmacology Fellowship Awards Selection Committee 1992-1995, Chairman 1994

American Federation for Aging Research
Research Committee 1986-1992
Fellowship Selection Committee 1993, 1994

Award Committee for Nellie Westerman Prize for Research in Ethics of the American Federation for Clinical Research, 1975-1978

USP - Delegate from Cornell University Medical College, 1975-1980
Advisory Panel on Geriatrics, Committee on Revision, 1980-1990

Consultant, Office of Technology Assessment, Congress of the United States, 1981

Consultant, New York State Department of Health, 1988-1992

Research Committee, American Federation for Aging Research, 1986-1992

Vice Chairman, Greater Philadelphia Committee for Medical-Pharmaceutical Sciences, 1968-1974

Representative of Pennsylvania Medical Society to Task Force on Drug Handling of the Commonwealth of Pennsylvania, 1968

UNICEF
Emergency Operations in former Yugoslavia, Advisor for Manual for Essential Drugs, 1994

USP DI-AMA DE Advisory Council, 1995-

SCIENTIFIC PUBLICATIONS

Associate Editor, Clinical Pharmacology and Therapeutics, 1980-1984
Editor, Clinical Pharmacology and Therapeutics, 1985-

EDITORIAL BOARDS

Primary Care, 1974-1979
Journal of Dialysis, 1976-1985
Clinical Pharmacokinetics, 1976-
Archives Internationales de Pharmacodynamie et de Therapie, 1976-
Pharmacology, 1978-1985
Clinical Pharmacology and Therapeutics, 1978-1980
Rational Drug Therapy, 1978-1985
Renal Physiology, 1978-1985
Therapeutic Drug Monitoring, 1978-
Trends in Pharmacological Sciences, 1978-
Clinical Nephrology, 1978-

BOOKS

Reidenberg, M.M.: Renal Function and Drug Action. Philadelphia, PA, W.B. Saunders Co., 1971.

Reidenberg, M.M., editor: Individualization of Drug Therapy. Medical Clinics of North America, Philadelphia, PA, W.B. Saunders Co., September, 1974.

Rubin, A.L., Stenzel, K.H., and Reidenberg, M.M., editors: Symposium on Drug Action and Metabolism in Renal Failure. Amer. J. Med., 62:459-563, 1977.

Reidenberg, M.M., editor: The Clinical Pharmacology of Symptom Control. Medical Clinics of North America, Philadelphia, PA, W.B. Saunders Co., September, 1982.

Lemberger, L. and Reidenberg, M.M., editors: Proceedings of Second World Conference on Clinical Pharmacology and Therapeutics. American Society for Pharmacology and Therapeutics, Bethesda, MD, 1984.

Reidenberg, M.M. and Erill, S., editors: Drug-Protein Binding. Praeger, New York, NY, 1986.

Reidenberg, M.M., editor: The Clinical Pharmacology of Biotechnology Products. Excerpta Medica, New York, NY, 1991.

Publications

Original Research in Refereed Journals

1. Hartman, J.D. and Reidenberg, M.M.: Comparison of the glycolytic activity of blood and exudate leucocytes. J. Appl. Physiol., 12:477-481, 1958.

2. Reidenberg, M.M., Ohler, E.A., and Sevy, R.W.: Cardiovascular responses to norepinephrine in acute adrenal insufficiency. Proc. Soc. Exper. Biol. and Med., 97:889-892, 1958.

3. Soloff, L.A., Reidenberg, M.M., Winters, W.L. Jr., and Bello, C.T.: Clinical experiences with bretylium tosylate. Ann. N.Y. Acad. Sci., 88(4):1003-1010, 1960.

4. Reidenberg, M.M. and Sevy, R.W.: Effect of adrenocortical steroids on bone electrolyte metabolism. Proc. Soc. Exper. Biol. and Med., 107:132-134, 1961.

5. Reidenberg, M.M., Ohler, E.A., Sevy, R.W., and Harakal, C.: Hemodynamic changes in adrenalectomized dogs. Endocr., 72:918-923, 1963.

6. Reidenberg, M.M. and Barry, W.E.: Low molecular weight dextran. Lancet, 1:988-989, 1964.

7. Adler, M.W., Reidenberg, M.M., Harakal, C., Rusq, B.F., and Papacostas, C.A.: Cardiovascular effects of hexafluorodiethyl ether. Int. J. Neuropsychiatry, 1:511-512, 1965.

8. Harakal, C., Reidenberg, M.M., Sevy, R.W., and Ohler, E.A.: Hemodynamic effects of adrenal medullectomy in the dog. Am. J. Physiol., 210:5-6, 1966.

9. Reidenberg, M.M., Haag, B.L., Channick, B.J., Shuman, C.R., and Wilson, G.G.: The response of bone to metabolic acidosis in man. Metabolism, 15:236-241, 1966.

10. Molthan, L., Reidenberg, M.M., and Eichman, M.F.: Positive direct Coombs' tests due to cephalothin. New Engl. J. Med., 277:123-125, 1967.

11. Barrera, F., Reidenberg, M.M., and Winters, W.L.: Pulmonary function in obese patients. Am. J. Med. Sci., 254:785-796, 1967.

12. Haag, B.L., Reidenberg, M.M., Shuman, C.R., and Channick, B.J.: Aldosterone, 17-ketosteroid, and fluid and electrolyte responses to starvation and selective refeeding. Am. J. Med. Sci., 254:652-658, 1967.

13. Reidenberg, M.M.: Registry of adverse drug reactions. Report of the drug reaction registry subcommittee of The Greater Philadelphia Committee for Medical-Pharmaceutical Sciences. J.A.M.A., 203:31-43, 1968.

14. Reidenberg, M.M., Sevy, R.W., and Cucinotta, A.J.: Hypercalciuria during acidosis in hypoparathyroidism. Proc. Soc. Exper. Biol. and Med., 127:1-3, 1968.

15. Harakal, C., Sevy, R.W., Reidenberg, M.M., and Faust, R.E.: Effect of adrenal medullectomy and total adrenalectomy on the hemodynamic responses to tyramine. J. Pharmacol. Exper. Ther., 160:292-299, 1968.

16. Reidenberg, M.M. and Lowenthal, D.T.: Adverse nondrug reactions. New Engl. J. Med., 279:678-679, 1968.

17. Reidenberg, M.M., Kostenbauder, H., and Adams, W.P.: The rate of drug metabolism in obese volunteers before and during starvation and in azotemic patients. Metabolism, 18:209-213, 1969.

18. Barrera, E.F., Reidenberg, M.M., Winters, W.L., and Hungspreugs, S.: Ventilation perfusion relationships in the obese patient. J. Appl. Physiol., 26:420-426, 1969.

19. Magargal, L.E., Magargal, H., and Reidenberg, M.M.: Effect of steroid hormones on the parathyroid hormone dose-response curve. J. Pharmacol. and Exper. Ther., 169(1):138-141, 1969.

20. Coleman, E.H. and Reidenberg, M.M.: Effect of thyroparathyroidectomy on skeletal sodium in the rat. Endocrinology, 85:175-176, 1969.

21. Glauser, S.C., Glauser, E.M., Reidenberg, M.M., Rusy, B.F., and Tallarida, R.J.: Metabolic changes associated with the cessation of cigarette smoking. Arch. Environ. Health, 20:377-381, March, 1970.

22. Reidenberg, M.M., Odar-Cederlof, I., Von Bahr, C., Borga, O., Sjoqvist, F.: Protein binding of diphenylhydantoin and desmethylimipramine in plasma from patients with poor renal function. New Engl. J. Med., 285:264-267, 1971.

23. Lowenthal, D.T. and Reidenberg, M.M.: The heart rate response to atropine in uremic patients, obese subjects before and during fasting, and patients with other chronic illnesses. Proc. Soc. Exper. Biol. and Med., 139(2):390-393, 1972.

24. Reidenberg, M.M., James, M., and Dring, L.G.: The rate of procaine hydrolysis in serum from normal subjects and diseased patients. Clin. Pharmacol. and Ther., 13:279-284, 1972.

25. James, M., Smith, R.L., Williams, R.T., and Reidenberg, M.M.: The conjugation of phenylacetic acid in man, subhuman primates, and some non-primate species. Proceedings of The Royal Society B, 182:25-35, 1972.

26. Reidenberg, M.M.: The procaine esterase activity of serum from different mammalian species. Proc. Soc. Exper. Biol. and Med., 140:1059-1061, 1972.

27. Drayer, D.E. and Reidenberg, M.M.: Metabolism of tetralin and toxicity of Cuprex(R) in man. Drug Metabolism and Disposition, 1:577-579, 1973.

28. Lowenthal, D.T., Chardo, F., and Reidenberg, M.M.: Removal of mercury by peritoneal dialysis. Arch. Int. Med., 134:139-141, 1974.

29. Reidenberg, M.M., Drayer, D.E., DeMarco, A.L., and Bello, C.T.:

Hydralazine elimination in man. Clin. Pharmacol. and Ther., 14:970-977, 1973.

30. Reidenberg, M.M., Shear, L., and Cohen, R.V.: Elimination of isoniazid in patients with impaired renal function. Am. Review of Respir. Dis., 108:1426-1428, 1973.

31. Reidenberg, M.M. and Martin, J.H.: The acetylator phenotype of patients with systemic lupus erythematosus. Drug Metabolism and Disposition, 2:71-73, 1974.

32. Kessler, K.M., Lowenthal, D.T., Warner, H., Gibson, T., Briggs, W., and Reidenberg, M.M.: Quinidine elimination in patients with congestive heart failure or poor renal function. New Engl. J. Med., 290:706-709, 1974.

33. Drayer, D.E., Reidenberg, M.M., and Sevy, R.W.: N-acetylprocainamide: An active metabolite of procainamide. Proc. Soc. Exper. Biol. and Med., 146:358-363, 1974.

34. Drayer, D.E., Strong, J.M., Jones, B., Sandler, A., and Reidenberg, M.: In vitro acetylation of drugs by human blood cells. Drug Metabolism and Distribution, 2:499-505, 1974.

35. Affrime, M. and Reidenberg, M.M.: The protein binding of some drugs in plasma from patients with alcoholic liver disease. Eur. J. Clin. Pharmacol., 8:267-269, 1975.

36. Reidenberg, M.M., Drayer, D.E., Levy, M., and Warner, H.: The polymorphic acetylation of procainamide by man. Clin. Pharmacol. Ther., 17:722-730, 1975.

37. Reidenberg, M.M. and Vesell, E.S.: Unaltered metabolism of antipyrine and tolbutamide during fasting in man. Clin. Pharmacol. Ther., 17:650-656, 1975.

38. Reidenberg, M.M. and Caccese, R.W.: Lymphocyte transformation tests and suspected drug allergy. J. Lab. Clin. Med., 86:997-1002, 1975.

39. Cerletti, C., Keinath, S.H., Reidenberg, M.M., and Adler, M.: Relationship between method of morphine administration, plasma levels, and the withdrawal syndrome in rats. Pharmacol., Biochem., and Behavior, 4:323-327, 1976.

40. Bagwell, E.E., Walle, T., Drayer, D.E., Reidenberg, M.M., Pruett, J.K.: Correlation of the electrophysiological and antiarrhythmic properties of the N-acetyl metabolite of procainamide with plasma and tissue drug concentrations in the dog. J. Pharmacol. Exper. Ther., 197:38-48, 1976.

41. White, R.P., Sealey, J., Reidenberg, M.M., Stenzel, K.H., Sullivan, J.F., David, D.S., Laragh, J.H., and Rubin, A.L.: Mechanisms of blood pressure control in anephrics: plasma renin and dopamine B hydroxylase activity. Trans. Amer. Soc. Artif. Int. Organs, 22:420-423, 1976.

42. Chami, J., Reidenberg, M., Wellner, D., David, D.S., Rubin, A., and Stenzel, K.H.: Essential amino acid metabolism in maintenance dialysis patients. Trans. Amer.Soc. Artif. Int. Organs, 22:168-173, 1976.

43. Reidenberg, M.M., Lowenthal, D.T., Briggs, W., and Gasparo, M.: Pentobarbital elimination in patients with poor renal function. Clin. Pharmacol. Ther., 20:67-71, 1976.

44. Drayer, D.E., Cordova, M., Slaven, B.H., Bagwell, E.E., and Reidenberg, M.M.: The antiarrhythmic activity of p-hydroxy-N-(2-diethylaminoethyl) benzamide (the p-hydroxy isostere of procainamide) in dogs and mice. J. Med. Chem., 20:270-274, 1977.

45. Tapia, L., Cheigh, J.S., David, D.S., Sullivan, J.F., Saal, S., Reidenberg, M.M., Stenzel, K.H., and Rubin, A.L.: Treatment of pruritus in dialysis patients with parenteral lidocaine. New Engl. J. Med., 296:261-262, 1977.

46. Szeto, H.H., Inturrisi, C.E., Houde, R., Saal, S., Cheigh, J., Reidenberg, M.M.: Accumulation of normeperidine, an active metabolite of meperidine, in patients with renal failure or cancer. Ann. Int. Med., 86:738-741, 1977.

47. Drayer, D.E., Lowenthal, D.T., Woosley, R.L., Nies, A.S., Schwartz, A., and Reidenberg, M.M.: Cumulation of N-acetylprocainamide, an active metabolite of procainamide, in patients with impaired renal function. Clin. Pharmacol. Ther., 22:63-69, 1977.

48. Saudek, C.D., Werns, S., and Reidenberg, M.M.: Phenytoin in the treatment of diabetic symmetrical polyneuropathy. Clin. Pharmacol. Ther. 22:196-199, 1977.

49. Drayer, D.E., Restivo, K., and Reidenberg, M.M.: Specific determination of quinidine and (3S)-3-hydroxyquinidine in human serum by high pressure liquid chromatography. J. Lab. Clin. Med., 90:816-822, 1977.

50. Romankiewicz, J.A., Reidenberg, M.M., Drayer, D.E., and Franklin, J.E.: The noninterference of aluminum hydroxide gel with quinidine sulfate absorption: An approach to control quinidine induced diarrhea. Amer. Heart J., 96:518-521, 1978.

51. Reidenberg, M.M., Levy, M., Warner, H., Coutinho, C.B., Schwartz, M.A., Yu, G., and Cheripko, J.: Relationship between diazepam dose, plasma level, age, and central nervous system depression. Clin. Pharmacol. Ther., 23:371-374, 1978.

52. Drayer, D.E., Lowenthal, D.T., Restivo, K.M., Schwartz, A., Cook, C.E., and Reidenberg, M.M.: Steady state serum levels of quinidine and active quinidine metabolites in cardiac patients with varying degrees of renal function. Clin. Pharmacol. Ther., 24:31-39, 1978.

53. Woosley, R.L., Drayer, D.E., Reidenberg, M.M., Nies, A.S., Carr, K., and Oates, J.A.: Effect of acetylator phenotype on the rate at which procainamide induces antinuclear antibodies and the lupus syndrome. New Engl. J. Med., 298:1157-1159, 1978.

54. Dietrich, J., Krauss, A.N., Reidenberg, M.M., Drayer, D.E., and Auld, P.A.M.: Alterations in state in apneic pre-term infants receiving theophylline. Clin. Pharmacol. Ther., 24:474-478, 1978.

55. Jones, B.R., Baran, A., and Reidenberg, M.M.: Evaluating patients' warfarin requirements. J. Amer. Geriatrics Soc., 28:10-12, 1980.

56. Meyers, T.F., Milsap, R.L., Krauss, A.N., Auld, P.A.M., and Reidenberg, M.M.: Low dose theophylline therapy in idiopathic apnea of prematurity. J. Ped., 96:99-103, 1980.

57. Lahita, R., Kluger, J., Drayer, D.E., Koffler, D., and Reidenberg, M.M.: Antibodies to nuclear antigens in patients treated with procainamide or acetylprocainamide. New Engl. J. Med., 301:1382-1385, 1979.

58. Drayer, D.E., Hughes, M., Lorenzo, B., and Reidenberg, M.M.: The prevalence of high (3S)-3-hydroxyquinidine/quinidine ratios in serum and the clearance of quinidine in cardiac patients of varying ages. Clin. Pharmacol. Ther., 27:72-75, 1980.

59. Jones, B.R., Bhalla, R.B., Mladek, J., Kaleya, R.N., Gralla, R.J., Alcock, N.W., Schwartz, M.K., Young, C.W., and Reidenberg, M.M.: Comparison of methods of evaluating nephrotoxicity of cis-platinum. Clin. Pharmacol. Ther., 27:557-562, 1980.

60. Kluger, J., Drayer, D., Reidenberg, M.M., Ellis, G., Lloyd, V., Tyberg, T., and Hayes, J.: The clinical pharmacology and antiarrhythmic efficacy of acetylprocainamide in patients with arrhythmias. Amer. J. Cardiol., 45:1250-1257, 1980.

61. Merle, L.J., Reidenberg, M.M., Camacho, M.T., Jones, B.R., and Drayer, D.E.: Renal injury in patients with rheumatoid arthritis treated with gold. Clin. Pharmacol. Ther., 28:216-222, 1980.

62. Reidenberg, M.M. and Restivo, K.: The binding of theophylline to serum proteins of hemodialysis patients. J. Dialysis, 3:375-381, 1979.

63. Cerletti, C., Keinath, S., Tallarida, R., Reidenberg, M.M., and Adler, M.W.: Morphine concentrations in the rat after intraperitoneal or subcutaneous injection. Substance and Alcohol Misuse, 1:65-70, 1980.

64. Reidenberg, M.M., Levy, M., Drayer, D.E., Zylber-Katz, E., and Robbins, W.C.: Acetylator phenotype in idiopathic systemic lupus erythematosus. Arthritis and Rheum., 23:569-573, 1980.

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